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Applicant(s): Davis

Application No.: 09/944,389

Filed: 9/4/2001

Title: Analytical Test Device and Immuno Assays and Methods of Using Same

Attorney Docket No.: IMIN.P-002-2

Group Art Unit: 1641

Examiner: Nguyen, Bao Thuy

Confirmation No.: 9864

Assistant Commissioner for Patents

Washington, D.C. 20231

RESPONSE UNDER 37 CFR 1.111

Dear Sir:

This is in response to the Office Action of July 26, 2002 for the above-captioned application. Reconsideration of the application in view of the remarks herein is respectfully requested.

Applicants thank the Examiner for her consideration of the priority claim in this instance and the indication that claims 26-82 are entitled to the benefit of the PCT filing date, namely 2/16/90. Applicants understand that this is not a determination with respect to whether these claims are entitled to the benefit of the British priority document which was filed on 2/17/89. Applicants believe that they are so entitled, which is why they provided a copy of this

I hereby certify that this paper and any attachments named herein are being deposited with the US Postal Service as first-class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on 28 Oct 2002.

Marina T. Larson
Marina T. Larson, PTO Reg. No. 32,038

28 Oct 02
Date of Signature

priority document with the previous response as Exhibit B thereto. This determination of priority is relevant in view of US Patents Nos. 5,252,496, 5,728,587 and 6,027,943 which are enclosed herewith, since the status of these applications as presumptive prior art¹ under 35 USC § 102(e) would depend on the validity of the priority claim to the British application.

Accordingly, the Examiner's comments on this issue are solicited.

The Examiner stated that claim 83 does not enjoy the support of the priority documents. Applicants respectfully disagree, and request reconsideration of this point. As is clear from the table provided with the response to restriction requirement filed May 20, 2002, Applicants do not assert that this claim gets the benefit of the British Priority date. However, the device configuration described in claim 83 is disclosed in the PCT application at Page 14, lines 24-35. Accordingly, this claim should be entitled to the benefit of the PCT filing date.

The Examiner stated that the IDS filed 9/04/01 failed to comply with 37 CFR § 1.98(a)(2) which requires copies of each document. Applicants point out that § 1.98(d) indicates that copies do not need to be provided in a continuation application where the references were of record in the parent case. This rule is applicable here, and the Examiner is requested to check the parent case file, since the non-patent references were not included in the file transferred to Applicants new attorney. However, to the extent that references are not available in the file, Applicant will endeavor to obtain new copies.

Applicants submit herewith a further Information Disclosure Statement listing the patents referred to above and two additional items. The first of the additional items is a Brief filed in connection with a motion for preliminary injunction in a litigation involving the parent case. The other additional item is a Declaration of Alan Schwartz filed in support of the Brief. The Brief and Declaration raise arguments relating to claim interpretation and validity which the Examiner may find of interest. The Examiner's attention is particularly directed to the Table on Pages 13-14 of the Schwartz Declaration where a comparison is made between claim 1 of the parent case and the Eisinger disclosure.

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Subject to antedating with an appropriate declaration and evidence.

While Applicants do not concede that the arguments made in these papers from the pending litigation are valid, Applicants would like to make sure that the record in this application is clear with respect to the meaning of the claims. Thus, Applicants point out that:

(1) the dry porous carrier and the macroporous body are different structures, distinguished by the difference in porosity as reflected in the claim language.

(2) the material from which the macroporous body is formed is not critical, provided that it is capable of receiving the labeled specific binding reagent in a manner that the labeled specific binding reagent is “freely mobile within the macroporous body when the macroporous body is wetted with the liquid sample” as stated in the claims. This is consistent with the Examiner’s broad reading of possible materials for the macroporous body in the rejections discussed below.

(3) In the flow path which is referenced in the claims, for example in claims 26 and 36, the specified elements do not have to be in contact with one another, but only have to be in the specified order. Thus, the term “sequential” in claim 36 refers to the order of the recited elements, and does not exclude intervening structures. This interpretation is consistent with and is fully supported by the written description in the specification, which notes, *inter alia*, that the sample must pass “through the [macroporous body] en route to the porous carrier” (Page 2, lines 33-35) and the disclosure of a specific embodiment in which it is stated that “ideally, the macroporous body is in direct moisture conductive contact with the porous material.” (Page 7, lines 12-14). By difference, if direct contact is ideal, then indirect fluid flow is encompassed in the broader concept. It should further be noted that the specification describes the porous carrier as being linked to the sample receiving member by the dry porous carrier. This does not require direct contact, or preclude intervening structures, since linked is defined on Page 10, lines 5-7, as “linked via the macroporous body such that any sample reaching the porous carrier must first pass through the macroporous body.”

On the final formal matter, the Examiner rejected the claims for double-patenting in view of the parent case. Applicants point out that a terminal disclaimer was included with the response to restriction requirement and the fee for a terminal disclaimer was paid. Thus, it is

believed that this issue is moot. For the completeness of the records, however, a further copy of this terminal disclaimer is attached as Exhibit A.

Turning to the merits, the Examiner rejected claims 26-36, 39-55, 58-74 and 77-82 as obvious over the combination of Rosenstein (US Patent No. 5,591,645) and Eisinger (US Patent No. 4,943,522). The Examiner has described Rosenstein as teaching an assay device which can be used in a sandwich assay format. The assay device has a substrate which has multiple portions. One of these portions is a tracer portion, on which a "tracer" which comprises a ligand portion and a label portion is placed. This tracer is conducted to a binder portion, where a binder effective to capture analyte is immobilized. The Examiner acknowledges that Rosenstein does not teach that the tracer portion is a macroporous body. The Examiner relies on Eisinger for a teaching of a non-bibulous material. Based on the pore sizes of the material, the Examiner equates this with a macroporous body, and asserts that it would be obvious to substitute this material for the tracer portion in Rosenstein.

Applicant's point out that the dry porous carrier and the macroporous body in the claimed invention are different materials (as reflected in the difference in the description of porosity). Thus, to render obvious the claimed invention, the Examiner would have to establish that the combination of references, considered without reference to the teachings of this invention, would have suggested replacing just the tracer portion, and not the other portions of Rosenstein substrate. Applicants respectfully submit that this conclusion cannot be reached based on the teaching of the references.

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In the Eisinger reference, the portion of the test device to which the capture reagent (Rosenstein's binder) is affixed is formed on the non-bibulous membrane. It is the specific binding reaction between this capture reagent and the analyte which is facilitated by the isotropic flow. Thus, there would be no reason based on Eisinger to use the non-bibulous material in place of a part of the Rosenstein device that did not include the binder portion. Furthermore, it should be noted that in Eisinger, the mobile reagent is not shown as being disposed on the non-bibulous strip, but rather on a separate pad or in a breakable container. Thus, Eisinger does not, taken as a whole, suggest using the non-bibulous material only as a

tracer portion and the combination of Rosenstein and Eisinger do not render the present invention unpatentable.

The Examiner also rejected claims 26-83 as obvious over the combination of May and Eisinger. Applicants assume that the Examiner meant to refer to May rather than Rosenstein in the statement of this rejection, and have treated the rejection accordingly. Nevertheless, this rejection is substantially similar to the rejection based on Rosenstein and Eisinger. In this case, the Examiner argues that it would be obvious to replace the part of the strip of May that contains the mobile reagent with the non-bibulous material of Eisinger. For the same reasons noted above, however, there is no reason **in the art** to make such a substitution. The non-bibulous material of Eisinger is always used in the part of the strip that contains the immobilized capture reagent. The mobile reagent is placed in a different location, which is exemplified as a different material. Thus, choosing to substitute the non-bibulous material of Eisinger for just the portion of May's strip which contains the mobile reagent is not a choice which is suggested in the art. Accordingly, this rejection should be withdrawn.

For the foregoing reasons, Applicants submit that all of the pending claims are in form for allowance. Favorable reconsideration and express confirmation that the priority date to which claims 26-82 are entitled is February 17, 1989 are respectfully requested.

Respectfully Submitted,


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